K011191

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

1.0 Date Prepared - April 18, 2001

JUN 2 6 2001

2.0 Submitter (Contact)

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Medtronic Xomed, Inc.
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3.0 Device Name

Proprietary Name: Merocel® Cornell Lid and Lash Guard

Common Name(s): Ophthalmic Sponge

Classification Name: Sponge Ophthalmic

4.0 Device Classification

Sponge Ophthalmic, Class II, 21 CFR 886.4790, Product Code: HOZ

5.0 Device Description

Merocel® Cornell Lid and Lash Guard is a thin ophthalmic sponge shaped to be used in conjunction with an eye specula.

6.0 Intended Use / Indications

Merocel® Cornell Lid and Lash Guard is an ophthalmic sponge for use during ophthalmic surgical procedures to absorb excess fluids. Used in conjunction with an eye specula, it is designed to provide a cushion between the eyelid and the specula, thus guarding the eyelid, the eyelid margin, and eyelashes from incidental contact with various ophthalmic instruments.

7.0 Substantial Equivalence

The Merocel® Cornell Lid and Lash Guard is considered to be substantially equivalent to competitive devices by M-Pact Worldwide Management Corporation's, and, Katena Product's based on intended use, performance characteristics, packaging, labeling, and sterilization.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 6 2001

Medtronic Xomed
C/O Diana Taylor
Sr. Regulatory Affairs Specialist
6743 Southpoint Dr. N.
Jacksonville, FL 32216-0980

Re: K011191
Trade/Device Name: Merocel® Cornell Lid and Lash Guard
Regulation Number: 886.4790
Regulatory Class: II
Product Code: HOZ
Dated: April 18, 2001
Received: April 19, 2001

Dear Ms. Taylor:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-6413. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Intended Use Statement

510(k) Number (if known): K011191

Device Name: Merocel® Cornell Lid and Lash Guard

Indications for Use:
Merocel® Cornell Lid and Lash Guard is an ophthalmic sponge for use during ophthalmic surgical procedures to absorb excess fluids. Used in conjunction with an eye specula, it is designed to provide a cushion between the eyelid and the specula, thus guarding the eyelid, the eyelid margin, and eyelashes from incidental contact with various ophthalmic instruments.

(Please do not write below this line - continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ Or Over-the-Counter Use _____

(Per 21 CFR 801.109) (Optional Format 1-2-96)

Karen Wabnitz

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K011191